REMARKS

Status of the Claims

Claims 24-56 are in the application.

Claims 24-56 were rejected. The rejection was made final.

Claims 24, 25, 28, 29, 38, 39, 47, 50-52, 55 and 56 have been amended, and claims 26, 27, 36, 37, 49 and 54 have been canceled.

Upon entry of this amendment, claims 24, 25, 28-35, 38-48, 50-53, 55 and 56 will be pending.

Summary of the Amendment

The claims have been amended to place them in condition for allowance. The amendments do not raise new issues. Therefore, entry of the amendment is proper.

Upon entry of the amendment, the claim set will consolidated and include two independent claims (claims 24 and 25) and twenty five dependent claims (claims 28-35, 38-48, 50-53, 55 and 56) of which each is dependent on either 24 or 25. Claim 24 and the claims dependent thereon (claims 28-35, 47, 48, 50 and 51) refer to a "method of treating an individual who has metastasized colorectal cancer". Claim 25 and the claims dependent thereon (claims 38-46, 52, 53, 55 and 56) refer to a "method of treating an individual who has been identified as being susceptible to metastasized colorectal cancer".

Claims 24 and 25 have each been amended to more clearly set forth the claimed subject matter. Claim 24 have each been amended to refer to the vaccine as an "expression vector", and to refer to the protein encoded by the nucleic acid as being a protein that comprises "the extracellular domain of human guanylyl cyclase C protein". Support for these amendments is found throughout the specification, claims as originally filed and canceled claims.

Claim 28, 29, 47, 48, 50 and 51 have been amended to make them each ultimately dependent on claim 24.

Claim 38, 39, 52, 55 and 56 have been amended to make them each ultimately dependent on claim 25.

Claims 26, 27, 36, 37, 49 and 54 have been canceled as either incorporated into the consolidated claim set or directed to subject matter which may be pursued in a divisional application.

No new matter has been added and no new issues will be raised upon entry of the amendment. The amendment places the claims in condition for allowance or in better condition for appeal. Entry of the amendment is respectfully requested.

Claim Rejection Under 35 U.S.C. § 112, first paragraph

Claims 24-56 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled for the full scope of the claims. The Office acknowledges that the specification enables "methods for treating individuals who have metastasized colorectal cancer or who have been identified as being susceptible to metastasized colorectal cancer comprising administering a therapeutically effective or prophylactically effective amount of an expression vector comprising a nucleic acid sequence encoding amino acids 24-454 as set forth in SEQ ID NO: 2." The Office alleges that in view of the definition provided in the specification, the terms "ST receptors" and "guanylyl cyclase C" refers to "ALL receptors found on colorectal cells which bind to ST." (Emphasis in original).

Claim 24 has been amended to refer to methods for treating individuals who have "metastasized colorectal cancer comprising the step of administering to such an individual a therapeutically effective amount of an expression vector comprising a nucleic acid sequence that encodes a protein comprising the extracellular domain of human guanylyl cyclase C protein."

Claim 25 has been amended to refer to methods for treating individuals who have been "identified as being susceptible to metastasized colorectal cancer comprising the step of administering to such an individual a prophylactically effective amount of an expression vector comprising a nucleic acid sequence that encodes a protein comprising the extracellular domain of human guanylyl cyclase C protein."

As amended, each of claims 24 and 25 correspond to the description of the subject matter acknowledged in the Official Action as being enabled with a single difference. Each of claims

24 and 25 refer to the protein as "comprising the extracellular domain of human guanylyl cyclase C protein". The Office has indicated that "guanylyl cyclase C" is being interpreted to be broader than the art recognized protein referred to as "guanylyl cyclase C" because of the passage in the specification which states:

> As used herein, the terms "ST receptor" and "guanylin cyclase C" are interchangeable and meant to refer to the receptors found on colorectal cells, including local and metastasized colorectal cancer cells, which bind to ST. In normal individuals, ST receptors are found exclusively in cells of intestine, in particular in cells in the duodenum, small intestine (jejunum and ileum), the large intestine, colon (cecum, ascending colon, transverse colon, descending colon and sigmoid colon) and rectum.

Applicant respectfully urges that when the specification is read in its entirety by those skilled in the art, it is apparent that both of the terms "ST receptor" and "guanylin cyclase C" are intended to refer to cellular receptors which are referred to by the art recognized, scientifically accepted name "guanylyl cyclase C". One skilled in the art would readily and clearly recognize that as used throughout the specification, the term "ST receptor" unambiguously is intended to be referring specifically and exclusively to guanylyl cyclase C, notwithstanding the cited passage or spelling errors in the specification. Applicant respectfully notes that the specification states:

> The nucleotide sequence that encodes human ST receptor protein is disclosed as SEQ ID NO:1. The amino acid sequence of human ST receptor is also disclosed in SEQ ID NO:1. Generally, the extracellular domain refers to the amino acids about 24 to about 454. The transmembrane region refers to amino acids about 455 to about 475. The cytoplasmic domain refers to amino acids about 476 to about 1093."

SEQ ID NO:1 contains the nucleic and amino acid sequences of human guanylyl cyclase C. When this cited passage is considered in view of this passage, it is unambiguous that the term "ST receptors" refer to "guanylyl cyclase C. Accordingly, the broader interpretation set forth by

the Office which suggests Applicant's reference to ST receptors and guanylyl cyclase C is somehow broader than the ordinary art recognized and accepted meaning of guanylyl cyclase C is incorrect. Accordingly, Applicant's suggested amendment of claims 24 and 25 to expressly refer to "the extracellular domain of guanylyl cyclase C" is enabled. Those skilled in the art would readily appreciate the meaning and scope of the claims and recognize that such clear and definite subject matter is fully enabled.

The dependency of each of claims 28, 29, 38, 39, 47, 50-52, 55 and 56 has been amended to render the each claim dependent upon either claim 24 or 25. The subject matter of each of claims 24, 25, 28-35, 38-48, 50-53, 55 and 56 is enabled.

Upon entry of the amendment, the rejection to the claims 24, 25, 28-35, 38-48, 50-53, 55 and 56 will be obviated. Applicant requests that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Conclusion

The amendment places the claims in condition for allowance and does not raise new issues. Upon entry of the amendment, claims 24, 25, 28-35, 38-48, 50-53, 55 and 56 will be in condition for allowance. Applicant respectfully requests that the amendment be entered and that a notice of allowance be earnestly solicited.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully submitted,

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